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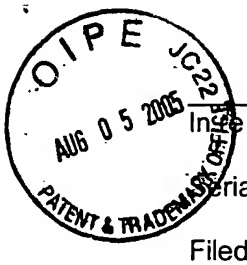

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Reissue Application of: Robert C. STEVENS

Serial No.: 10/075,053 Group Art Unit: 3763

Filed: February 13, 2002 Examiner: Kevin C. Sirmons

For: **REINFORCED CATHETER DEVICE, CATHETER STOCK, AND METHODS AND APPARATUS FOR MAKING SAME**

Attorney Docket No.: RSTZ 2 00011-3

MAIL STOP Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF
APPEAL BRIEF UNDER 37 C.F.R.§1.192

Dear Sir:

Applicant transmits herewith three (3) copies of APPEAL BRIEF UNDER 37 C.F.R.§1.192 for the above-reference patent application.

Payment in the amount of $250.00 for the filing of this Appeal Brief is authorized to be charged to a Credit Card. The appropriate form PTO-2038 is enclosed for this purpose. If the Credit Card is unable to be charged, please charge any and all fees or credit any overpayment to Deposit Account No. 06-0308.

Respectfully submitted,

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I certify that this **Appeal Brief** Under 37 C.F.R. 1.136(a) and accompanying document(s) are being

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APPEAL BRIEF
Under 37 C.F.R. § 1.193(b)(1)

This is an Appeal to the Board of Patent Appeals and Interferences from the decision of the Examiner contained in the Office Action mailed from the U.S. Patent and Trademark Office on December 3, 2004 in connection with the above-identified matter.

I. REAL PARTY IN INTEREST

The present application was assigned to Mrs. Carol J. Stevens, an individual, on December 3, 2003 from the original sole inventor and applicant Mr. Robert C. Stevens, and is also now licensed to AngioDynamics, Inc., a Delaware corporation located at 603 Queensbury Avenue, Queensbury, NY 12804.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the appellant's legal representative(s), or licensee which will directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

The claims appealed are as follows:

a) claims 1, 3-11 (catheter apparatus);

b) 24, 26-28 (catheter stock for manufacturing catheters); and,

c) claims 41-51 (catheter apparatus).

A statement of the status of all claims is as follows:

Claim 1	Pending – rejected
Claim 2	Canceled
Claim 3	Pending – rejected
Claim 4	Pending – rejected
Claim 5	Pending – rejected
Claim 6	Pending – rejected
Claim 7	Pending – rejected
Claim 8	Pending – rejected
Claim 9	Pending – rejected
Claim 10	Pending – rejected
Claim 11	Pending – rejected
Claim 12	Withdrawn
Claim 13	Withdrawn
Claim 14	Withdrawn
Claim 15	Withdrawn
Claim 16	Withdrawn
Claim 17	Withdrawn
Claim 18	Withdrawn
Claim 19	Withdrawn
Claim 20	Withdrawn
Claim 21	Withdrawn
Claim 22	Withdrawn
Claim 23	Withdrawn
Claim 24	Pending – allowed
Claim 25	Canceled
Claim 26	Pending – allowed
Claim 27	Pending – allowed
Claim 28	Pending – allowed
Claim 29	Withdrawn
Claim 30	Withdrawn
Claim 31	Withdrawn
Claim 32	Withdrawn
Claim 33	Withdrawn
Claim 34	Withdrawn
Claim 35	Withdrawn

Claim 36	Withdrawn
Claim 37	Withdrawn
Claim 38	Withdrawn
Claim 39	Withdrawn
Claim 40	Withdrawn
Claim 41	Pending – allowed
Claim 42	Pending – allowed
Claim 43	Pending – allowed
Claim 44	Pending – allowed
Claim 45	Pending – allowed
Claim 46	Pending – allowed
Claim 47	Pending – allowed
Claim 48	Pending – allowed
Claim 49	Pending – allowed
Claim 50	Pending – allowed
Claim 51	Pending – allowed

IV. STATUS OF AMENDMENTS

A statement of the status of any amendment(s) filed subsequent to the final rejection is presented below.

A First Response After Final Rejection was filed by telefacsimile in this matter on February 23, 2005. A copy of the Auto-Reply Facsimile Transmission Confirmation Sheet from the United States Patent and Trademark Office confirming that all forty-two (42) pages were received on February 23, 2005 is included with this Appeal Brief at Exhibit 1.

As of the date of this Appeal Brief, the Examiner has not responded in any way to the first Response After Final Rejection filed more than five (5) months ago. A Notice of Allowance/Allowability has not yet been received by appellant. Accordingly, as far as appellant is concerned, the status of that Response is "not entered" which is a factor in motivating this Appeal and is believed to be a reasonable assumption for purposes of the arguments resented in this Appeal. The Official status of the Response, however, is unknown to Appellant because the Examiner has not provided anything in the record to show that he considered that Response.

In any case, as to the Board's review of this Appeal, the First Response After Final Rejection filed more than five (5) months ago and unanswered by the Examiner did not present any amendments to the claims because the claims are believed to be patentable over the art of record. Overall, the First Response After Final

Rejection was limited t a restatement of appellant's earlier arguments in an effort to assist in clarifying the issues for the Examiner.

In addition to filing a First Response After Final Rejection, appellant filed a Statement of Substance of Interview on May 3, 2005 together with a Notice of Appeal. The Statement and Notice papers were received at the U.S. Patent and Trademark Office on May 5, 2005. The Statement of Substance of Interview paper presented no claim amendments and, like the Response After Final Rejection, was unanswered by the Examiner. The purpose of the Statement of Substance of Interview was to assist the Examiner. A copy of an Office Action Summary Sheet "Supplemental to Interview Summary" prepared by the Examiner is attached at Exhibit 2 and shows that the Examiner considered claims 24 and 26-28 to be allowed.

V. SUMMARY OF INVENTION

The Present Application:

A first embodiment of the invention is directed to a reinforced catheter apparatus (claims 1, 3-11, and 41-51) and a second embodiment of the invention is directed to a reinforced catheter stock for manufacturing reinforced catheters (claims 24 and 26-28). The first and second embodiments of the invention forming the instant application are the subjects of the instant Appeal. A third embodiment of the invention directed to a method of manufacturing multiple reinforced catheters (claims 12-23), a method of manufacturing a reinforced catheter stock (claims 29-33), and a fourth embodiment is directed to an apparatus for manufacturing the reinforced catheter stock (claims 34-40). The third and fourth embodiments of the invention in the instant application are not subjects of this Appeal and have been previously withdrawn.

First Embodiment:

As noted above, a first embodiment of the invention is directed to a reinforced catheter apparatus. Essentially, the apparatus includes an elongate tubular member carrying a continuous coil reinforcement member thereon from end to end. First and second layers of outer coatings are disposed onto the tubular member and coil reinforcement in turn so that the first material forms a first layer thereon and the second material forms a second layer on the first material. The inner first material is

softer than the outer second material. A portion of the second outer coating is ground away to form a flexible distal tip portion of the catheter.

The reinforced catheter apparatus 68 is shown in Figure 4b as amended (Exhibit 3) and is described in the specification, particularly at page 14. The reinforced catheter 68 comprises an elongate flexible tubular member 51 defining a lumen of the catheter, a continuous coil reinforcement member 54 (Fig. 2c) carried on the elongate flexible tubular member 51, a first flexible outer coating 58 covering the coil reinforcement member 54, and a second flexible outer coating 62 covering a first portion 74 of the first outer coating 58. The elongate flexible tubular member 51 defining the lumen of the catheter has a first end defining a proximal end 69 of the catheter, and a second end defining a distal end 67 of the catheter. The continuous coil reinforcement member 54 (Fig. 2c) carried on the elongate flexible tubular member 51 extends from the proximal end 69 of the catheter to the distal end 67 of the catheter. The first outer coating 58 covers the coil reinforcement member 54 and the tubular member 51 substantially entirely between the proximal end 69 of the catheter and the distal end 67 of the catheter. The second flexible outer coating 62 covers a first portion 74 of the first outer coating 58 between a first transition area 73 of the catheter and the proximal end 69 of the catheter. A second portion 72 of the first outer coating 58 is uncovered by the second outer coating 62 and defines a flexible tip 72 of the catheter. Lastly, in the first preferred embodiment, the first outer coating 58 is softer than the second outer coating 62.

In independent claim 41, yet a further reinforced catheter 68 is recited comprising an elongate flexible tubular member 51 defining a lumen of the catheter, the tubular member 51 having a first end defining a proximal end 69 of the catheter and a second end defining a distal end 67 of the catheter, a first flexible outer coating 58 covering the tubular member 51 from the proximal end 69 of the catheter to the distal end 67 of the catheter, a second flexible outer coating 62 covering a first portion 74 of the first outer coating 58 with a second portion 72 of the first outer coating 58 being uncovered by the second outer coating 62 and defining a flexible distal tip 67 of the catheter, the first coating 58 being softer than the second coating 62, and a coil reinforcement member 54 (Fig. 2c) carried on the elongate flexible tubular member 51 and disposed at the distal tip 67 of the catheter.

Second Embodiment:

In accordance with a second embodiment of the application, a reinforced catheter stock is provided for forming multiple catheters therefrom. The catheter stock includes a tubular member carrying a continuous coil reinforcement member thereon. First and second buildups of first and second material layers are disposed thereon wherein the first inner layer is softer than the second outer layer. The catheter stock may be cut into pieces to provide catheters having selected lengths as desired.

In the second embodiment of the application, the reinforced catheter stock 64 is provided for manufacturing reinforced catheters. The catheter stock 64 is constructed in accordance with a method as set out in the specification and shown in flow chart form in Fig. 1. It is to be appreciated that selected method steps from Fig. 1 are illustrated in various drawing figures including Figs. 2a-2f. The end product resultant from the method shown in Fig. 1 is a reinforced catheter stock construction 64 as shown in Fig. 2f. More particularly, the reinforced catheter stock 64 (Fig. 2f) comprises a selected length of an elongate flexible tubular member 51 (Fig. 2a) defining a lumen of the catheter stock. The tubular member has a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock. A continuous coil reinforcement member 54 (Figs. 2b-2f) is carried on the elongate flexible tubular member 51 (Figs. 2b-2f) and extends from the lead end of the catheter stock to the trailing end of the catheter stock. A continuous outer coating of a first material 58 (Fig. 2e) covers the coil reinforcement member 54 and the tubular member substantially entirely between the lead end of the catheter stock and the trailing end of the catheter stock. Further, a continuous outer coating of a second material 62 (Fig. 2f) covers the continuous outer coating of the first material 58 substantially entirely between the lead end of the catheter stock and the trailing end of the catheter stock. In the second embodiment of the invention, the first material 58 is softer than the second material 62.

VI. ISSUES

A concise statement of the issues presented for review is as follows below. The issues are:

1) whether U.S. Patent No. 5,972,143 to Stevens anticipates claims 1, 2, 6-11, 24, 25, 17, and 28;

2) whether U.S. Patent No. 5,972,143 to Stevens renders claims 3 and 26 obvious;

3) whether U.S. Patent No. 5,972,143 to Stevens in view of U.S. Patent No. 5,147,315 to Weber renders claim 4 obvious; and,

4) whether U.S. Patent No. 5,972,143 to Stevens in view of U.S. Patent No. 5,147,315 to Weber and further in view of U.S. Patent No. 5,843,051 to Adams, et al. renders claim 5 obvious.

VII. GROUPING OF CLAIMS

The First Ground of Rejection:

Claims 1, 2, 6-11, 24, 25, 17, and 28 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,972,143 to Stevens.

Applicant contests this ground of rejection and hereby states that the claims of this group do not stand or fall together for at least the following reasons set out below.

First, claims 2 and 25 were rejected by the Examiner as being anticipated by Stevens were previously canceled by applicant and were not pending at the time of the final Office Action. Claims 2 and 25 were not to be included in the examined claim set for purposes of the Office Action of February 9, 2005.

Further, claim 17 was rejected by the Examiner as being anticipated by Stevens was previously withdrawn from consideration as being directed to a non-elected invention. Claim 17 was not to be included in the examined claim set for purposes of the Office Action of February 9, 2005.

Claims 1 and 6-11 are directed to a reinforced catheter apparatus and are patentable over the Stevens patent and further are separately patentable over the remaining claims in this group.

Claims 24 and 28 are directed to a reinforced catheter stock for manufacturing reinforced catheters and are believed to be patentable over the Stevens patent and separately patentable over the remaining claims in this group.

Thus, it is respectfully submitted that among the group of claims identified by the Examiner as being anticipated by Stevens (claims 1, 2, 6-11, 24, 25, 17, and 28), claims 1 and 6-11 stand or fall together and claims 24, 28 stand and fall together.

These claims are directed to an individual reinforced catheter apparatus having a proximal end and a distal end and having a first transition area between the proximal and distal ends. The remaining claims in the group of claims in the first ground of rejection, however, are directed to a reinforced catheter stock useful for the manufacture of multiple individual catheters. The catheter stock has a first and second end and a continuous coil reinforcement member extending between the ends. The reinforced catheter stock does not include a transition area because the stock is for purposes of manufacturing multiple catheters which each individually have a transition area.

The Second Ground of Rejection:

Claims 3 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens.

Claim 3 is directed to a reinforced catheter and is believed to be patentable over Stevens and separately patentable from claim 26.

Claim 26 is directed to a reinforced catheter stock for manufacturing reinforced catheters and is believed to be patentable over Stevens and separately patentable from claim 3.

Therefore, with regard to the rejection of these claims as being unpatentable over Stevens, it is respectfully submitted that claim 3 stands or falls alone and claim 26 stands or falls alone.

The Third Ground of Rejection:

Claim 4 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,147,315 to Weber.

Thus, it is respectfully submitted that as to the rejection of claim 4 as being unpatentable over Stevens in view of Weber, claim 4 stands or falls alone.

The Fourth Ground of Rejection:

Claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of Weber and further in view of U.S. Patent No. 5,843,051 to Adams, et al.

Thus, it is respectfully submitted that as to the rejection of claim 5 as being unpatentable over Stevens in view of Weber and further in view of Adams, et al., claim 5 stands or falls alone.

Allowed Claims 41-51:

Claims 41-51 were added into the record of this application as new claims presented for examination in the Amendment filed on September 7, 2004. The Amendment was received at the U.S. Patent and Trademark Office and date stamped on September 10, 2004.

The Examiner has not identified or applied any prior art against those claims. Therefore, they are patentable by law in accordance with reasons and arguments set out below.

Claims 41-51 are directed to a reinforced catheter apparatus and are separately patentable from the remaining claims pending in the instant application.

VIII. ARGUMENT

Claims 1 and 3-11 are in Condition for Allowance:

Independent claim 1 recites a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member carried on the flexible tubular member, and first and second outer coatings covering the coil reinforcement member, the first coating being softer than the second coating. The elongate flexible tubular member defines a lumen of the catheter and has a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. The continuous coil reinforcement member is carried on the elongate flexible tubular

member and extends from the proximal end of the catheter to the distal end of the catheter. The first outer coating covers the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter. The second flexible outer coating covers a first portion of the first outer coating between a first transition area of the catheter and the proximal end of the catheter. The second portion of the first outer coating is uncovered by the second outer coating and defines a flexible distal tip of the catheter.

It is respectfully submitted that the prior art of record does not teach or suggest a construction of a reinforced catheter including a continuous coil reinforcement member extending from the proximal end of the catheter to the distal end of the catheter. More particularly, in the primary reference cited by the Examiner, namely, the Stevens '143 patent, it is respectfully submitted that there is no teaching of a reinforcement member extending from one end of the catheter to the other. Rather, in the Stevens '143 patent, the reinforcement member is removed from the distal end of the catheter by grinding it away or otherwise removing it to provide a very flexible tip.

In the prior art Stevens '143 patent, the reinforcement member is not continuous from the proximal end of the catheter to the distal end. The dictionary definitions of the terminologies "end", "from", and "to" are set out below for the convenience of the Board and the Examiner.

Dictionary Definitions:

End: 1. Either extremity of something that has length

From: 1.a. Used to indicate a specified place or item as a starting point.

1.b. Used to indicate a specified point as the first of two limits.

To: 1.a. In a direction toward so as to reach: *went to the city.*

1.b. Toward: *turned to me.*

The limitation in the claim of "continuous" is clear, that is, the reinforcement member is uninterrupted and extends from the proximal end of the catheter to the distal end. The dictionary definition below shows that the expression "from" is used to indicate a specified place or item as a starting point. Thus, the proximal end of the catheter is a starting point for the continuous reinforcement member

to extend. The expression "end" is a limitation in the claim and means either extremity of something that has length. In addition, the continuous coil reinforcement member recited in the claim extends to the distal end of the catheter which, as set out in the dictionary definition below means that it extends to the extremity of the catheter so as to reach the extremity.

Again, the primary art reference cited by the Examiner of the Stevens '143 patent shows a discontinuous reinforcement member which does not extend continuously between the extreme ends of the catheter. In addition, neither the Weber nor the Adams, et al. patent cited by the Examiner teach, suggest, or fairly disclose a continuous coil reinforcement member extending from a distal to a proximal end and first and second coatings wherein the first coating is softer than the second coating.

In addition to the above, it is respectfully submitted that the prior art of record does not teach or suggest a construction of a catheter including a continuous coil reinforcement member extending between the proximal and distal ends of the catheter and being coated by a first material and a second material wherein the first material is softer than the second material. More particularly, in the primary reference cited by the Examiner, namely the Stevens '143 patent, it is respectfully submitted that there is no teaching of first and second continuous flexible coatings covering a coil reinforcement member with the outer coating being harder than the inner coating. At best, in the Stevens '143 patent, the extruded thin coat is meant simply to adhere the braided steel reinforcement member onto the underlying tubular body. In addition to the above, nowhere in the Stevens '143 patent is there a teaching that the hardness of the bonding layer relative to the outer coating is of any significance. Still further, in the Stevens '143 patent, a portion of the stainless steel reinforcement member is ground away prior to the application of the single outer flexible coating. Thus, the reinforcement member in the prior art does not extend fully between the proximal end of the catheter and the distal end of the catheter. In addition, neither of the Weber nor Adams, et al. patents teach or suggest these limitations.

The above limitations are clearly recited in independent claim 1 as amended above. For at least these reasons, it is respectfully submitted that independent claim 1 and claims 3-11 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 24 and 26-28 are in Condition for Allowance:

Independent claim 24 recites a reinforced catheter stock for manufacturing reinforced catheters. The catheter stock comprises a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock; a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and, a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

Again, it is respectfully submitted that the art of record does not teach or suggest a catheter stock for making a reinforced catheter having a continuous coil reinforcement member extending from one end of the catheter to the opposite end and having first and second outer coatings of first and second materials, respectfully, covering the coil reinforcement member wherein the outer coating is harder than the inner coating and a portion of the outer coating being selectively removable from the inner coating to expose a soft distal tip portion of the catheter.

The Examiner has misconstrued the Stevens '143 patent. More particularly, reference is directed to Figures 2a-2f of the Stevens '143 patent whereat a catheter stock construction sequence is illustrated. Figure 2a shows a first layer 10 deposited onto a mandrill and in Figure 2b a braided reinforcement member is wrapped thereon. In Figure 2c, a plurality of spaced apart bonding layer portions are provided 14, 16, 18 so that selected spaced apart portions of the reinforcement wire can be removed by a grinding process without causing fraying to occur in the reinforcement wire. As shown in Figure 2d, the reinforcement wire is selectively ground away from the structure at locations 30, 32, and 34 to provide a discontinuous reinforcement member

along the length of the catheter stock. Thereafter, one or more outer cover layers are deposited onto the discontinuous formations of the braided reinforcement member.

The reinforced catheter stock recited in independent claim 24 clearly includes the limitation of a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the head end of the catheter stock to the trailing end of the catheter stock. The reinforcement member taught in the Stevens '143 patent, however, is clearly discontinuous as shown in Figure 2d. In the Stevens '143 patent, the outer coating layers are applied after the discontinuity is created in the reinforcement member. In the construction recited in independent claim 24, however, the coil reinforcement member is continuous and is covered by outer coatings of first and second materials.

Neither the Weber or Adams, et al. patents teach, suggest, or fairly disclose a reinforced catheter stock for use in manufacturing multiple catheter devices. Rather, each of those patents teach individual catheters having various features thought to be interesting to the Examiner. None, however, teach a reinforced catheter stock.

For at least the above reasons, it is respectfully submitted that independent claim 24 as amended above and claims 26-28 dependent therefrom are patentable distinct and unobvious over the art of record.

Claims 41-51 are in Condition for Allowance:

Independent claim 41 recites a reinforced catheter comprising a elongate flexible tubular member, a first outer coating covering the tubular member, a second flexible outer coating covering a first portion of the first outer coating, and a coil reinforcement member carried on the elongate flexible tubular member and disposed at a distal tip of the catheter. The elongate flexible tubular member defines the lumen of the catheter and includes a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. The first flexible outer coating covers the tubular member from the proximal end of the catheter to the distal end of the catheter. The second flexible outer coating covers a first portion of the first outer coating while a second portion of the first outer coating remains or is otherwise

uncovered by the second outer coating and defines a flexible distal tip of the catheter. In claim 41, the first coating is softer than the second coating.

As noted above in connection with the prior art cited by the Examiner, U.S. Patent No. 5,972,143 to Stevens teaches a catheter including a coiled reinforcement member covered in a practical sense by only a single flexible outer coating. The coil reinforcement does not extend the entire length of the catheter but, however, is removed from a distal tip portion thereof.

Independent claim 41 recites a catheter having a coil reinforcement member disposed at a distal tip portion thereof. This is, of course, contrary to the teachings of the Stevens '143 patent which, as noted above, includes a coil reinforcement member in a portion of the catheter but not in the distal tip portion thereof.

In addition to the above, appellant respectfully submits that a person shall be entitled to a patent unless the invention was known or used by others before the invention thereof by the applicant for the patent, the invention was patented or published more than one year prior to the filing date, he has abandoned the invention and for various other reasons set out by statute in 35 U.S.C. § 102. Thus, the appellant in this application is entitled to a patent unless it is sufficiently demonstrated to the contrary. Clearly the Examiner has not presented any information which would contradict applicant's entitlement to a patent on these claims.

For at least the above reasons, applicant respectfully submits that independent claim 41 and claims 42-51 dependent therefrom are patentably distinct and unobvious over the art of record.

IX. APPENDIX

Listing of Claims:

A copy of the claims involved in the Appeal is as follows:

1. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter to the distal end of the catheter;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter; and,

a second flexible outer coating covering a first portion of the first outer coating between a first transition area of the catheter and said proximal end of the catheter, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating.

2. (Canceled)

3. (Previously Presented) The reinforced catheter according to claim 1 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

4. (Original) The reinforced catheter according to claim 1, further comprising a marker band disposed adjacent the distal end of the catheter on the outer coating.

5. (Original) The reinforced catheter according to claim 4, wherein the marker band is formed of a one of gold material and platinum material.

6. (Original) The reinforced catheter according to claim 1, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

7. (Original) The reinforced catheter according to claim 1, wherein the continuous coil reinforcement member is a stainless steel wire.

8. (Original) The reinforced catheter according to claim 1, wherein the continuous coil reinforcement member defines a helical pattern.

9. (Original) The reinforced catheter according to claim 1, wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

10. (Original) The reinforced catheter according to claim 1, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

11. (Original) The reinforced catheter according to claim 1, wherein the second outer coating is comprised of a nylon material.

12. (Withdrawn) A method of manufacturing multiple reinforced catheters comprising the steps of:

providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members;

providing a selected length of a reinforcement wire;

for substantially the length of the cylindrical tube, advancing the cylindrical tube from the first spool member to the second spool member while simultaneously wrapping the reinforcement wire onto said portion of the cylindrical tube between the first and second spool members to form a continuous length of reinforced catheter stock;

coating the reinforced catheter stock with a predetermined thickness of a first coating and followed by a second coating harder than said first coating for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock; and,

cutting the coated catheter stock at selected locations corresponding to desired catheter lengths to form a plurality of reinforced catheters.

13. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12 further including the step of grinding the second coating of any one or more of said plurality of reinforced catheters to expose a portion of the first coating and to provide a desired outer surface finish and a desired flexibility along the longitudinal length of the catheter.

14. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 13 further including the step of swaging a marker band around the outer surface of the coating at a distal end of the any one or more of said plurality of reinforced catheters.

15. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 14, wherein the step of swaging the marker band includes swaging a marker band formed of one of a group of materials consisting of gold and platinum.

16. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 14, wherein the grinding step includes grinding a portion of the catheter beginning at a first end defining a distal end of the catheter for a predetermined distance along the longitudinal length of the catheter toward a second end defining a proximate end of the catheter.

17. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 16, wherein the grinding step includes grinding the portion of the catheter such that the thickness of the finish coating at the distal end of the catheter is less than the thickness of the finish coating at the proximate end of the catheter.

18. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 17, further including the step of coating a ground portion of the catheter with a predetermined thickness of a soft finish coating.

19. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 18, wherein the step of coating the ground portion with said soft finish coating includes coating the ground portion with a urethane material.

20. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the cylindrical tube is a polytetrafluoroethylene (PTFE) material.

21. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the reinforcement wire is a stainless steel wire.

22. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the wrapping step includes wrapping said reinforcement wire onto said cylindrical tube in a helical pattern.

23. (Withdrawn) The method of manufacturing multiple reinforced catheters according to claim 12, wherein the coating step includes coating the reinforced catheter stock with a predetermined thickness of said first coating followed by a predetermined thickness of said second coating, the first coating having a Shore hardness of about 40D and said second coating having a Shore hardness of about 70D.

24. (Previously Presented) A reinforced catheter stock for manufacturing reinforced catheters, the catheter stock comprising:

a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock;

a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock;

a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and,

a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

25. (Canceled)

26. (Previously Presented) The reinforced catheter stock according to claim 24, wherein:

the continuous coil reinforcement member defines a helical pattern;

the first material has a Shore hardness of about 40D; and,

the second material has a Shore hardness of about 70D.

27. (Original) The reinforced catheter stock according to claim 24, wherein the elongate flexible tubular member is a polytetrafluoroethylene (PTFE) material.

28. (Original) The reinforced catheter stock according to claim 24, wherein the continuous coil reinforcement member is a stainless steel wire.

29. (Withdrawn) A method of manufacturing a reinforced catheter stock, the method comprising the steps of:

providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members;

providing a selected length of a reinforcement wire; and

while advancing the cylindrical tube from the first spool member to the second spool member, wrapping the reinforcement wire onto the cylindrical tube at a

point between the first and second spool members for substantially the length of the cylindrical tube to form a continuous length of reinforced catheter stock.

30. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 27, further comprising the step of coating the reinforced catheter stock with a predetermined thickness of a first finish coating then a second finish coating harder than said first finish coating for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock.

31. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the step of providing said elongate cylindrical tube includes providing a polytetrafluoroethylene (PTFE) material.

32. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the step of providing said selected length of said reinforcement wire includes providing stainless steel wire.

33. (Withdrawn) The method of manufacturing reinforced catheter stock according to claim 29, wherein the wrapping step includes wrapping said reinforcement wire onto said cylindrical tube in a helical form.

34. (Withdrawn) An apparatus for manufacturing reinforced catheter stock, the apparatus comprising:

a first support member and a second support member, the first and second support members being spaced apart and carrying an elongate cylindrical tube with a portion of the cylindrical tube extending between the first support member and the second support member;

a winder device carrying a selected length of a reinforcement member, the winder device being adapted to wind the reinforcement member onto the cylindrical tube at a point between the first and second support members; and,

a control device simultaneously controlling i) advancement of the cylindrical tube relative to the winder device and ii) winding the reinforcement member onto said cylindrical tube by the winder device at the point between the first and second support members.

35. (Withdrawn) The apparatus according to claim 34, wherein said first support member includes a pay-out spool and said second support member includes a take-up spool, the pay-out spool and the take-up spool being responsive to the control device to pay out the elongate cylindrical tube from the pay-out spool and onto the take-up spool.

36. (Withdrawn) The apparatus according to claim 34, wherein the elongate cylindrical tube is a polytetrafluoroethylene (PTFE) material.

37. (Withdrawn) The apparatus according to claim 34, wherein the winder device includes:

a coiler tip member defining i) a central bore adapted to receive said cylindrical tube at the point between the pair of spaced apart support members, and ii) an offset opening carrying said reinforcement member, the coiler tip member being selectively rotatable relative to said cylindrical tube to wind the reinforcement member onto the cylindrical tube at selected varied angles relative to a plane perpendicular to a longitudinal axis of the cylindrical tube.

38. (Withdrawn) The apparatus according to claim 37, wherein the winder device further includes:

a motor for rotating the coiler tip member relative to the cylindrical tube;

a spool for carrying the reinforcement member; and,

a tubular member adapted to rotate with the coiler tip member to feed the reinforcement member from said spool and through the offset opening of the coiler tip member as the reinforcement member is wound onto the cylindrical tube.

39. (Withdrawn) The apparatus according to claim 38, wherein the winder device is adapted to wind the reinforcement member onto the cylindrical tube in a helical pattern.

40. (Withdrawn) The apparatus according to claim 34, wherein the reinforcement member is comprised of a stainless steel wire.

41. (Previously Presented) A reinforced catheter comprising:

an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;

a first flexible outer coating covering the tubular member from the proximal end of the catheter to the distal end of the catheter;

a second flexible outer coating covering a first portion of the first outer coating, a second portion of the first outer coating being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating; and,

a coil reinforcement member carried on the elongate flexible tubular member and disposed at said distal tip of the catheter.

42. (Previously Presented) The reinforced catheter according to claim 41, wherein said coil reinforcement member is carried on said tubular member from said distal end of the catheter to said proximal end of the catheter.

43. (Previously Presented) The reinforced catheter according to claim 42 wherein:

said first flexible outer coating has a Shore hardness of about 40D; and,

said second flexible outer coating has a Shore hardness of about 70D.

44. (Previously Presented) The reinforced catheter according to claim 41, further comprising a marker band disposed adjacent the distal end of the catheter on the outer coating.

45. (Previously Presented) The reinforced catheter according to claim 44, wherein the marker band is formed of a one of gold material and platinum material.

46. (Previously Presented) The reinforced catheter according to claim 41, wherein the elongate flexible tubular member is formed of a polytetrafluoroethylene (PTFE) material.

47. (Previously Presented) The reinforced catheter according to claim 41, wherein the continuous coil reinforcement member is a stainless steel wire.

48. (Previously Presented) The reinforced catheter according to claim 41, wherein the continuous coil reinforcement member defines a helical pattern.

49. (Previously Presented) The reinforced catheter according to claim 41, wherein a thickness of the distal end of the catheter is less than a thickness of the proximal end of the catheter.

50. (Previously Presented) The reinforced catheter according to claim 41, wherein the first outer coating is comprised of one of a group of materials consisting of nylon material and urethane material.

51. (Previously Presented) The reinforced catheter according to claim 41, wherein the second outer coating is comprised of a nylon material.

CONCLUSION

In view of the above comments and arguments presented, appellant respectfully submits that all pending claims are allowable over the references of record.

Allowance of all claims and early notice to that effect is respectfully requested.

Respectfully submitted,

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STATEMENT OF SUBSTANCE OF INTERVIEW

EXHIBIT 2

Supplemental to Interview Summary

Office Action Summary	Application No.	Applicant(s)	
	10/075,053	STEVENS, ROBERT C.	
	Examiner	Art Unit	
	Kevin C. Sirmons	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *N/A* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-24 and 26-40* is/are pending in the application.

4a) Of the above claim(s) *12-23 and 29-40* is/are withdrawn from consideration.

5)☒ Claim(s) *24 and 26-28* is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

EXHIBIT 3

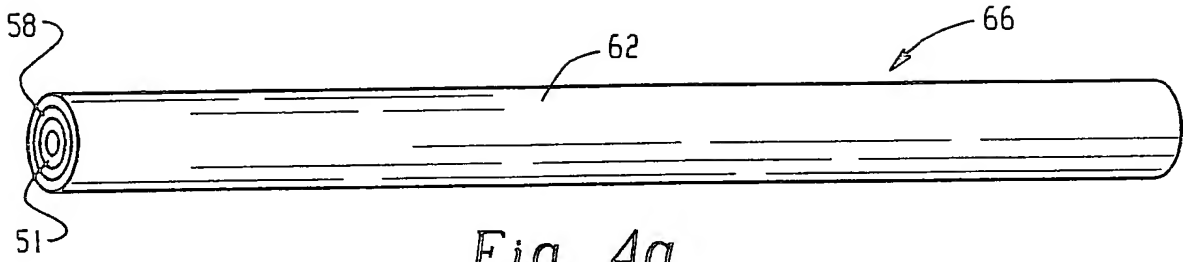

Fig. 4a

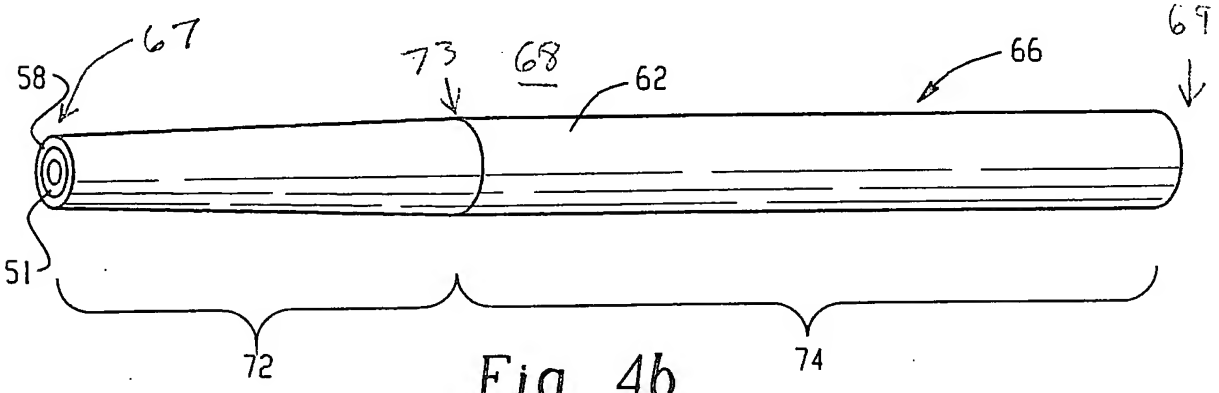

Fig. 4b

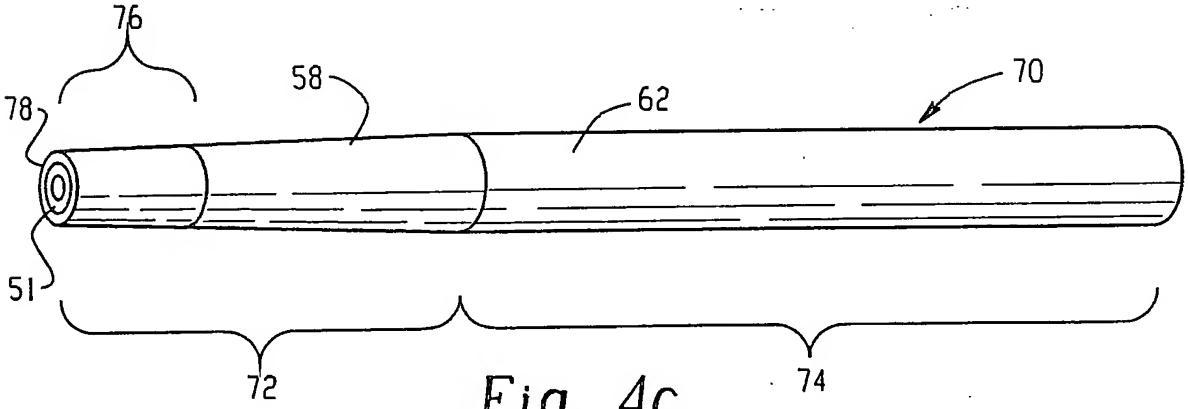

Fig. 4c

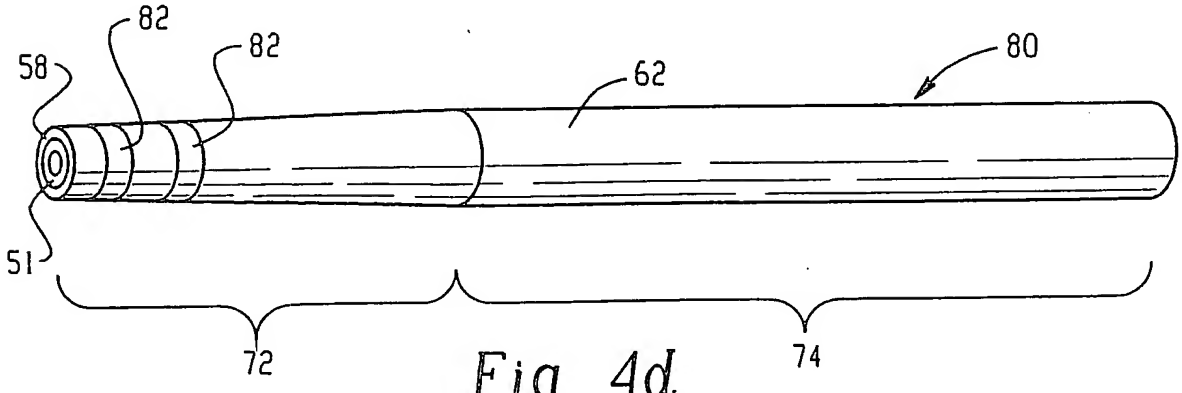

Fig. 4d